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Florian Thaler

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EXAMINER

NOLAN, JASON MICHAEL

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,675	Applicant(s) THALER ET AL.	
	Examiner JASON NOLAN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 12 is/are allowed.
- 6) ☒ Claim(s) 10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment, filed 03/18/2009. Claims 7, 10, 12, & 13 are pending in the instant application, all of which are currently amended. Claims 1-6, 8, 9, 11, & 14-16 are cancelled.

Response to Amendments & Arguments

Applicant's Declaration, filed under Rule 132, is acknowledged and has been considered. Applicant's amendments with respect to Claims 7, 10, 12, & 13 have been fully considered and are entered. The 101/112 "use of" rejection of Claim 9 has been withdrawn per amendment. The 102 prior art rejections of Claims 7, 8, & 10-16 have been withdrawn per amendment (the second proviso in Claim 7). The 112 enablement rejection of Claims 7, 8, & 10-16 has been withdrawn per amendment and argument. The ODP rejection of Claims 7 & 12 over US 5,912,242 is withdrawn per amendment (the first proviso in Claim 7); however, the ODP rejection is maintained over Claims 10 & 13 for the reasons infra.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10 & 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-9 of U.S. Patent No. 5,912,242 (the '242 patent).

As per MPEP 804, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ 2d 1290 (Fed. Cir. 1991); *In re*

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Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). For this reason, the factual inquires set forth in *Graham v. John Deere Co.*, 383 U.S. 1, USPQ 459 (1966) are employed. These factual inquires are summarized as follows: (A) Determining the scope and contents of the patent claim relative to a claim in the application at issue; (B) Ascertaining the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue; (C) Determine the level of ordinary skill in the pertinent art; and, (D) Evaluate any objective indicia of nonobviousness.

(A). *Determining the scope and contents of the patent claim relative to a claim in the application at issue* – the scope and content of Claims 1-9 in the '242 patent include the species in Claim 9 that are identical to and included in instant Claim 10, the pharmaceutical compositions in Claim 5, and a method of treating a neurodegenerative disease in Claim 9. Thus, the claims as a whole include using the same compounds to those in the instant application in a method of treating neurodegenerative disorders, (a class of diseases which is not mutually exclusive from the diseases recited in the instant Claim 13).

The term neurodegenerative disease is a generic term for a class of disorders characterized by gradual and progressive loss of neural tissue. As such, there are more than 600 neurological disorders. Brown *et al. Environmental Health Perspectives* 2005, 113(9), 1250-1256. On one hand, some of the diseases listed in the instant Claim 13 fall within the scope of neurodegenerative disease. For instance, cognitive disorders such as dementia exist in Alzheimer's disease patients. See Sydney-Smith's

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presentation: Neurodegenerative Disease, at the International Summit for Mental Health, March 2009. On the other hand, some of the diseases listed in the instant Claim 13 are symptoms of neurodegenerative disease. Since the diagnosis of neurodegenerative disease has been elusive, often requiring postmortem examination to determine a confident diagnosis, one solution has been to monitor neurological symptoms. Brown *et al.* 2005. Brown states, “Known risk factors for neurodegenerative disease include . . . inflammation, stroke, hypertension, diabetes . . .”

Further, there is evidence that the same or similar potential drug candidates may treat neurodegenerative disease, pain, inflammation, and cognitive disorders. Fischer *et al. Neurodegenerative Diseases* 2004, 1, 50-70. The drug in entry 65 shows a calcium channel blocker that is useful for the treatment of neurodegenerative disease.

(B) Ascertaining the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue – Claim 8 of the '242 patent recites the term “neurodegenerative disease,” whereas Claim 13 of the instant application recites, “pain, migraine, cognitive disorders, inflammation . . . obesity.” Such diseases are considered to one of ordinary skill in the art to either fall within the scope of or to be symptoms of neurodegenerative disease. For the reasons identified supra, the term neurodegenerative disease either includes or logically flows from the diseases listed in the instant Claim 13.

(C) Determine the level of ordinary skill in the pertinent art – the level of ordinary skill in the art may be found by inquiring into: (1) the type of problems encountered in the art; (2) prior art solutions to those problems; (3) the rapidity with which innovations

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are made; (4) the sophistication of the technology; and (5) the education level of active workers in the field. *Custom Accessories, Inc.*, 807 F.2d at 962. All of those factors may not be present in every case, and one or more of them may predominate. *Env'tl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed.Cir.1983). Based on the typical education level of active workers in the field of organic chemistry, biochemistry, pharmacology, and biology, as well as the high degree of sophistication required to solve problems encountered in the art, the Examiner finds that a person of ordinary skill in the art would have at least a college degree in the field of one of said fields and at least four years of work experience, i.e. a masters or doctorate level scientist.

(D) *Evaluate any objective indicia of nonobviousness* – there is no evidence that the same species in the '242 patent (Claim 9) used to treat neurodegenerative disease (Claim 8) would not be useful for treating the disorders considered either within the scope of neurodegenerative disease or as a symptom monitored for diagnosing neurodegenerative disease (instant Claim 13 and overlapping species in Claim 10).

Conclusion - Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to subject matter that is considered to not be mutually exclusive.

Allowable Subject Matter

Claims 7 & 12 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is Jason.Nolan@uspto.gov. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The USPTO fax number for applications is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information

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Retrieval (PAIR) system, (either Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626